



General

Guideline Title

ACR Appropriateness Criteria® indeterminate renal mass.

Bibliographic Source(s)

Heilbrun ME, Casalino DD, Beland MD, Bishoff JT, Blafox MD, Coursey CA, Goldfarb S, Harvin HJ, Nikolaidis P, Preminger GM, Raman SS, Sahni VA, Vikram R, Weinfeld RM, Remer EM, Expert Panel on Urologic Imaging. ACR Appropriateness Criteria® indeterminate renal mass [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 11 p. [72 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Israel GM, Casalino DD, Remer EM, Arellano RS, Bishoff JT, Coursey CA, Dighe M, Egli DF, Fulgham P, Goldfarb S, Lazarus E, Leyendecker JR, Nikolaidis P, Papanicolaou N, Prasad S, Ramchandani P, Sheth S, Vikram R, Expert Panel on Urologic Imaging. ACR Appropriateness Criteria® indeterminate renal masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2010. 7 p. [66 references]

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Indeterminate Renal Masses

Variant 1: Patient with normal renal function.

Radiologic Procedure	Rating	Comments	RRL*
CT abdomen without and with contrast	9	Either CT or MRI is appropriate. Use thin-section CT.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
MR imaging without and with contrast	4,5,6	Either CT or MRI is appropriate. See statement regarding contrast in the text below under "Anticipated	Relative Radiation Level

Radiologic Procedure	Rating	Exceptions. Comments	RRL*
US kidney retroperitoneal with duplex Doppler	8		O
Biopsy renal mass	5		Varies
MRI abdomen without contrast	3	This procedure can be useful to characterize simple cysts.	O
Arteriography kidney	1		<input type="text"/> <input type="text"/> <input type="text"/>
X-ray intravenous urography	1		<input type="text"/> <input type="text"/> <input type="text"/>
CT abdomen without contrast	1		<input type="text"/> <input type="text"/> <input type="text"/>
CT abdomen without contrast	1		<input type="text"/> <input type="text"/> <input type="text"/>
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 2: Patient with renal insufficiency (contraindication to intravenous contrast).

Radiologic Procedure	Rating	Comments	RRL*
US kidney retroperitoneal with duplex Doppler	8		O
MRI abdomen without contrast	7		O
Biopsy renal mass	6		Varies
CT abdomen without contrast	5	This procedure may be useful to detect fat in AMLs or attenuation value in cysts.	<input type="text"/> <input type="text"/> <input type="text"/>
MRI abdomen without and with contrast	3	This procedure is rated higher than CT because the incidence of NSF is less than the incidence of CIN.	O
CT abdomen without and with contrast	2	This procedure is rated lower than MRI because the incidence of CIN is greater than the incidence of NSF.	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
CT abdomen without contrast	1		<input type="text"/> <input type="text"/> <input type="text"/>
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative

X-ray intravenous urography Radiologic Procedure	Rating	Comments	RRL*
Arteriography kidney	1		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

An indeterminate renal mass is one that cannot be diagnosed confidently as benign or malignant at the time it is discovered. Lesions or masses whose character and type are clearly defined by the first imaging test will not be discussed in this review.

Renal masses are increasingly detected in asymptomatic individuals as incidental findings. Computed tomography (CT), ultrasonography (US), and magnetic resonance imaging (MRI) of renal masses with fast-scan techniques and intravenous (IV) gadolinium are the mainstays of evaluation. Dual-energy CT, contrast-enhanced US, positron emission tomography (PET)/CT, and percutaneous biopsy are all technologies that are gaining traction in the characterization of the indeterminate renal mass.

Computed Tomography

CT is the most utilized imaging technique for evaluating the indeterminate renal mass, playing an important role in the characterization of both solid and cystic lesions. Although the majority of lesions are characterized on initial imaging, one definition for the indeterminate renal mass is a lesion containing areas that measure 20–70 Hounsfield units (HU) on noncontrast imaging. Homogeneous lesions measuring <20 HU or >70 HU can be considered benign, whereas lesions either entirely or partially within the 20–70 HU range should be considered indeterminate and warrant further evaluation. In those lesions requiring further evaluation, enhancement after IV contrast is key in determining if a renal mass warrants treatment. Enhancing solid renal masses or enhancing components in cystic masses indicates a vascularized mass and, therefore, a possible malignancy. The degree of renal enhancement is dependent on many factors, including the amount and rate of contrast material injection, the timing of contrast-enhanced imaging, and the intrinsic characteristics of both the mass and the adjacent renal parenchyma. Sensitivity of CT in identifying small renal masses is >90%. Proper characterization of a renal mass includes at least 3 phases: noncontrast imaging followed by contrast-enhanced imaging in corticomedullary and nephrographic phases.

Cystic Renal Masses

The criteria for complex or indeterminate cysts are based on attenuation and contrast enhancement. Less than 10 HU increase in attenuation between noncontrast and contrast-enhanced imaging is considered to be within the technical limits of the study and thus is not significant. With the introduction of helical and multidetector CT scanners, the degree of pseudoenhancement can exceed 20 HU. Although the evidence from phantom and retrospective clinical studies suggests that a threshold of 20 HU change may be rational, many still treat a change in attenuation in the 10–20 HU range as indeterminate and suggest that additional imaging, biopsy, or surveillance may be warranted.

The Bosniak CT classification system for cystic renal masses encompasses the spectrum from simple renal cyst to obvious cystic malignancy, with the likelihood of malignancy increasing with the complexity of the mass. One retrospective review found that the overall incidence of renal cell carcinoma (RCC) in 71 surgically treated cystic lesions was 0% in category II, 20% in category IIF, 55.6% in category III, and 76.9% in category IV. Another review found a malignancy rate in excised Bosniak IIF and Bosniak III cystic renal lesions of 25% and 54%, respectively. A cyst that contains simple fluid (0–20 HU), has a hairline-thin wall, does not contain septa or calcification, and does not enhance with IV contrast is considered category I, a benign cyst. Category II cysts have a hairline-thin wall and may contain a few hairline-thin septa. A hairline-thin calcification or a short segment of slightly thickened but smooth calcification may be seen in category II lesions. These lesions do not show measurable enhancement with IV contrast. Initial reports indicated that category II cysts are invariably benign. Hyperattenuating cysts (>20 HU) with sharp, smooth margins that do not enhance with contrast are included in category II lesions. The hyperdense cyst can present a diagnostic problem in that its initial attenuation coefficients are high, which can theoretically obscure tiny papillary projections along its wall. However, a homogeneous renal mass measuring >70 HU at unenhanced CT has been shown to have a >99.9% chance of representing a high-attenuation renal

cyst rather than RCC.

Category IIF cysts are those cystic renal masses that are felt to be benign but are too complex to be diagnosed with absolute certainty. They have one or more of the following abnormalities: increased number of hairline-thin septa; minimal thickening of cyst wall or septa, which may demonstrate perceived (not measurable) enhancement of septa or cyst wall; calcification, which may be thick and nodular; no enhancing soft-tissue components; and totally intrarenal high-attenuation lesions ≥ 3 cm in size. These lesions, in view of their complexity when compared to category II lesions, warrant follow-up (usually at 6-month intervals for the first year, and then annually for a minimum of 5 years), to assure stability. No specific follow-up interval has been found to definitively diagnose a mass as benign. However, in one series 95% (40/42) of category IIF lesions with a minimum of 2-year follow-up were stable (>5 -year mean follow-up), whereas in the remaining 5% (2/42) the lesions were eventually diagnosed as RCC. There is high interpersonal variability in the classification of category II and IIF lesions.

Category III lesions are by definition indeterminate in that they cannot be classified as benign or malignant on imaging. These lesions have grossly thickened walls or septa in which measurable enhancement can be demonstrated. The differential diagnosis for category III lesions includes diagnoses such as multilocular cystic RCC, multilocular cystic nephroma, multilocular hemorrhagic cyst, and chronic renal abscess. Because malignancy cannot be excluded in these cases surgery is usually suggested (with the exception of a chronic renal abscess). In recent surgical and biopsy series the malignancy rate in category III lesions is between 28% and 54%.

Solid Renal Masses

The differential diagnosis for solid renal masses includes RCC and benign lesions such as minimal fat angiomyolipomas (AMLs) and oncocytoma. The percentage of benign tumors in surgical and biopsy series is approximately 20% and increases as the size of the lesions decrease. A single-center large retrospective surgical series found that the proportion of benign tumors increased from 5% to more than 20% during the previous 2 decades. CT detection of small amounts of fat defines the benign AML. Fat related to other malignant neoplasms has been reported, but these masses are generally large tumors that have engulfed perinephric or renal sinus fat or are renal carcinomas that have areas of osseous metaplasia and small amounts of fat. Approximately 5% of AMLs contain little or no fat and have the appearance of small hyperattenuating (at unenhanced CT) homogeneously enhancing indeterminate masses, making these lesions indistinguishable from RCC. A recent retrospective cohort study of 70 renal masses <4 cm, of which 12 were oncocytomas, found that arterial phase enhancement greater than 500% and washout values greater than 50% are exclusively seen in renal oncocytomas. CT findings of homogeneity or a central stellate "scar" are poor discriminators in predicting oncocytoma or RCC, regardless of size. It remains uncertain if there are sufficiently specific features to distinguish oncocytomas from RCC such that surgery could be avoided.

The small (≤ 1.5 cm in diameter) renal mass poses a more complex problem for CT imaging, in that volume-averaging effects occur, making it difficult to assess accurately the density on noncontrast images and to evaluate for enhancement after IV contrast administration. In a multidetector CT study of 37 patients with 175 small (<3 cm) renal masses, thin overlapping reconstructions were performed and compared to routine 5 mm thick sections to determine if the thin overlapping reconstructions could improve detection and characterization of small renal masses. Lesion characterization for cysts improved from 29% to 84% when thin overlapping reconstructions were used, and the overall percentage of indeterminate lesions was reduced from 69% to 53%.

Dual-energy CT technologies have been applied to distinguish enhancing from nonenhancing or equivocally enhancing renal lesions. Current studies have suggested that dual-energy CT may be a highly specific technique for excluding enhancement and moderately to highly sensitive in detecting enhancement of renal lesions. Limitations of this technique are related to the quality of the virtual unenhanced imaging (VNE), which is slightly inferior to true nonenhanced image sets. Attenuation levels on the VNE images may be slightly higher than the levels measured on acquired nonenhanced images, although this difference does not result in significant misclassification of benign and malignant lesions. Others have suggested that the variability in attenuation values in solid organs, including renal parenchyma, on VNE images compared to true unenhanced images, raises concerns about the validity of this modality if the requirement for determining enhancement is an absolute change in attenuation between VNE and contrast-enhanced CT attenuation values. Additionally, lesions found in patients with high body mass indices may be more difficult to assess on the virtual noncontrast images.

Magnetic Resonance Imaging

MRI using IV gadolinium contrast agents now provides sensitivity and specificity similar to that of CT in detecting contrast enhancement and identifying a mass requiring surgery. Because nephrogenic systemic fibrosis is associated with the IV administration of gadolinium in patients with renal insufficiency the use of contrast may be inappropriate in those patients with indeterminate renal masses and known renal dysfunction. Gadolinium is still felt to be safe in patients with a history of allergy to iodinated contrast agents.

One group of researchers demonstrated that it is possible to calculate percentage of enhancement of renal masses at MRI and that this can be used to characterize renal masses. In another study, 73 patients with 93 renal masses underwent contrast-enhanced MRI, and quantitative enhancement with signal intensity measurement analysis (percentage enhancement) was compared to qualitative analysis of enhancement with image subtraction

to determine which was superior for detecting malignancy. Sensitivity and specificity for diagnosing malignancy based on enhancement were 95% and 53%, respectively, for quantitative analysis and 99% and 58%, respectively, for qualitative analysis. Three of four malignant lesions incorrectly assigned as benign by quantitative method were hyperintense on unenhanced MRI. All were accurately diagnosed as malignant by qualitative method. The benign lesions that were misclassified were the oncocytomas.

In a study of 69 cystic renal masses evaluated using the Bosniak classification with CT and MRI, there was CT and MRI agreement in 56 of 69 lesions (81%) and disagreement in 13 of 69 lesions (19%). CT and MRI were felt to be similar in evaluation of most renal cystic mass lesions. However, MRI may depict additional findings such as an increase in number of septa, septal and/or wall thickness, and enhancement. Such findings would result in MRI upgrading cystic lesions and thus might alter patient management. It may be difficult to confidently categorize complex cystic renal masses on MRI, more specifically those that are borderline between categories IIF and III, without additional correlative imaging.

For AMLs that do not contain macroscopic fat, chemical-shift MRI may suggest the diagnosis by demonstrating loss of signal on the opposed-phase images. Although clear-cell RCC may also lose signal on opposed-phase MRI, these lesions tend to be characterized by higher T2 signal intensity than AMLs with minimal fat. On one study of multiparametric MRI, AMLs with minimal fat were characterized by higher T1 signal intensity compared to normal renal cortex, lower T2 signal intensity compared to normal renal cortex, and greater arterial-to-delayed enhancement ratio than RCC. It remains a challenge to distinguish minimal fat AMLs from RCC based on MR features.

Ultrasonography

US plays an important role in the detection and characterization of renal masses. US is often sufficient as a standalone modality to characterize category I renal cysts. The criteria for US diagnosis of renal cysts are well-defined. To diagnose renal cysts via US, the mass must be sonolucent, demonstrate good through-transmission of the sound waves with posterior enhancement, and have a thin, well-defined wall. Complex masses not fulfilling the criteria of cysts are considered indeterminate and require further evaluation, usually by CT. US may be useful in characterizing some of these high-attenuation lesions, as approximately 50% of them will be anechoic and can be characterized as benign.

Factors limiting US include the patient's body habitus, lesion location, multiple lesions, and calcification in the wall of a cystic mass and hemorrhagic fluid in a cystic mass. Color and power Doppler imaging have shown improved and promising results in characterizing renal masses. In one study of 114 patients, phase-inversion harmonic imaging, when combined with B-mode sonography, improved lesion conspicuity as well as accuracy in tissue characterization. Doppler US has been suggested as a way to further characterize solid masses; in the absence of clinical evidence of infection, a Doppler frequency shift >2.5 kHz is advocated by some as a reliable indicator of malignancy.

Contrast-enhanced Doppler US using IV-administered contrast agents has also been shown to have the potential to improve the detection and characterization of RCCs, but it is not widely available in the United States. A European multireader series compared sonography without contrast material and sonography with the IV injection of sulfur hexafluoride-filled microbubbles for the characterization of 40 complex cystic renal masses found on CT. With the task of defining a lesion as benign or malignant, the overall diagnostic accuracy of contrast-enhanced sonography was better than unenhanced sonography and CT for all readers. Accuracy for unenhanced sonography was only 30%, compared to 80% to 83% for contrast-enhanced sonography and 63% to 75% for CT. Another European study of 143 lesions showed that contrast-enhanced US could predict malignancy with a sensitivity, specificity, positive, negative predictive value and accuracy of 97%, 45%, 91%, 75%, and 90%, respectively. Contrast-enhanced US was superior to CT in the staging and characterization of RCC as well as in the subgroup of patients with cystic lesions. These authors suggested that contrast-enhanced US might replace CT in those subjects with contrast allergies or other contraindications to contrast-enhanced CT (CECT).

Biopsy

Biopsy of the indeterminate renal mass is experiencing resurgence in interest and acceptance, especially in a mass <4 cm. In the last few years, in part due to the development of new techniques in histological and molecular analysis, the indications for renal mass biopsy have increased and now include confirmation of RCC when the surgical risk is high, when disease is either locally advanced or metastatic, when a solid mass is present in a solitary or transplant kidney, prior to ablative therapies, and when alternative diagnoses, including infection, lymphoma, or metastatic disease are considerations. Decision-modeling studies have suggested that percutaneous biopsy is cost-effective and may play a greater role in the future in the diagnosis and management of the indeterminate renal mass. At one United States institution, one-third of patients presenting with small renal masses undergo renal mass biopsy; this is most common in patients with complicated anatomic and/or tumor considerations. Given that benign disease may be more frequent than imaging would suggest, as seen in one series of 58 small, indeterminate renal biopsy cases that found that 27% were benign, alternatives to definitive treatment should be considered. The biopsy results are used to guide decision-making aimed at minimizing total kidney loss with active surveillance being chosen more frequently among patients with benign or favorable histology. One of the limitations of biopsy has been the rate of nondiagnostic results. In a case series of 345 percutaneous biopsy cases, the biopsy was diagnostic in 278 cases (80.6%), of which 94.1% were RCC. When repeat biopsy was undertaken in 15 of the initial 67 nondiagnostic samples, 11 (73%) were malignant. Thus, the authors suggest that a nondiagnostic biopsy cannot be considered evidence of benignity.

Nuclear Medicine

Fluorine-18-2-fluoro-2-deoxy-D-glucose positron emission tomography (FDG-PET) may prove useful in detecting renal tumors and characterizing indeterminate renal cysts. Questions related to the diagnostic accuracy of and low sensitivity of FDG-PET for RCC detection and characterization has limited its use for this purpose.

Angiography

Although two-thirds of renal tumors have enough vascularity to allow identification of tumor neovascularity, one-third will be of such a hypovascular or "avascular" state that angiography will not help identify the lesion as benign or malignant.

Intravenous Urography

Abdominal radiographs have very poor sensitivity and specificity for evaluating a renal mass. IV urography with nephrotomography has only 67% sensitivity in detecting renal masses ≤ 3 cm in diameter, and without tomography the sensitivity is even less. It is rarely used in current management of the indeterminate renal mass. This technique has largely been replaced with CT urography for the evaluation of patients with hematuria. This test provides a comprehensive evaluation of the urinary tract and not only can detect renal calculi and masses but also can evaluate the urothelial tract for causes of hematuria.

Active Surveillance

Active surveillance as a diagnostic strategy for the small indeterminate renal mass is gaining some traction in more current epidemiologic series. The low malignant and metastatic potential of small RCCs (≤ 4 cm in diameter) is supported by many series. In the elderly or a patient who is a poor surgical risk, it may be appropriate to follow small solid masses with serial imaging rather than perform surgery because of the competing risk of comorbid diseases on overall survival. However, analyses of the Surveillance, Epidemiology and End Results (SEER) database have found a survival benefit after nephrectomy compared to nonsurgical management, even when controlling for age, tumor size, and year of diagnosis. No specific size threshold for growth over time has been shown to reliably predict which indeterminate masses are malignant and which are benign. Thus, the optimal diagnostic and management strategy remains uncertain.

Because of the uncertain malignant potential of the incidentally detected renal masses, a "wait and see" approach is especially appropriate for managing the very small, asymptomatic, indeterminate renal mass in an elderly patient. If the patient's clinical condition militates against surgery or if there is surgical risk of causing the patient to become dialysis-dependent, such lesions, because of their low metastatic potential when small, can be followed with CT or MRI. For a younger, healthy patient, a solid mass >1 cm is usually surgically treated (except for AML). Although there are no data to suggest how to manage very small (<1 cm) renal masses, some feel that if the lesion in question appears to be a simple cyst—i.e., a low-attenuation (0–20 HU) mass containing no septations, nodularity, calcifications, or enhancement—it can be presumed to be benign and need not be further pursued.

Patients with Renal Insufficiency (Contraindication to IV Contrast)

The inability to utilize IV contrast to evaluate a renal mass markedly limits whether it can be classified as benign or malignant on CT. This may apply to patients with allergies to IV contrast or renal insufficiency, such that patients are placed at increased risk of contrast induced nephropathy (iodinated CT contrast) or nephrogenic systemic fibrosis (gadolinium-based MR contrast). These issues should be considered when serum creatinine is ≥ 2.0 mg/dL or estimated glomerular filtration rate (eGFR) is <30 mL/min/1.73m². In the absence of contrast, MRI has some advantages over CT in the characterization of renal masses. Simple cystic lesions or even those with thin septations can often be characterized on the T2-weighted imaging based on their very high T2 signal intensity. Diffusion-weighted imaging, although less accurate than contrast-enhanced MR imaging, has some ability to differentiate solid RCCs from oncocytomas and characterize the histologic subtypes of RCC. New and specialized MRI sequences have been proposed for the purposes of characterizing the vascularity of renal lesions in patients with renal dysfunction. For example, one small study of 17 renal lesions used arterial spin labeling to detect blood flow in renal masses, which correlated with malignancy. Low-fat AMLs tend to be lower in T2 signal intensity than non-AMLs. An angular interface with the renal parenchyma to T2-weighted imaging has been shown to be a highly sensitive and specific (78% and 100%, respectively) finding for differentiating benign exophytic renal masses from malignant masses. As described above, the US demonstration of a sonolucent mass with good through-transmission of the sound waves with posterior enhancement and a thin, well-defined wall is reassuring. Complex masses not fulfilling the criteria of cysts are considered indeterminate and require further evaluation. US may be useful in characterizing some of these high-attenuation lesions, as approximately 50% of them will be anechoic and can be characterized as benign.

Summary

- CT is the modality of choice for evaluating indeterminate renal lesions that are suspicious for malignancy.

- For those patients who cannot tolerate iodinated IV contrast material due to allergy, MRI with gadolinium contrast is advised.
- US may be useful to clarify a mass seen on CT that is probably a hyperdense cyst and is the modality of choice if IV contrast is contraindicated.
- MRI appears to be more sensitive than CT and tends to upgrade cystic lesions. Thus, some caution is advised when using MRI findings to direct clinical management at this time.
- Renal biopsy is gaining acceptance and is increasingly used in characterizing and managing renal masses. Accepted indications include confirming an infected cyst, identifying lymphoma or a metastasis as the cause of the indeterminate renal mass, and confirming RCC in certain circumstances, including prior to ablative therapies, when a solid mass is present in a solitary or transplant kidney, or when disease is either locally advanced or metastatic.
- Active surveillance also plays a role in diagnosing the indeterminate renal mass, especially in older patients or those with significant comorbidities in whom the risk of alternative causes of mortality may be greater than the risk of mortality from possible RCC.

Anticipated Exceptions

Contrast-induced nephrotoxicity (CIN) is a sudden deterioration in renal function following the recent intravascular administration of iodinated contrast medium in the absence of another nephrotoxic event. There is consensus that the most important risk factor for CIN is pre-existing renal insufficiency. In patients with acute kidney injury, the administration of iodinated contrast medium should only be undertaken with appropriate caution and only if the benefit to the patient clearly outweighs the risk. Patients with acute kidney injury are particularly susceptible to nephrotoxin exposure and therefore it is probably prudent to avoid intravascular iodinated contrast medium in these patients (when possible), regardless of the generally low nephrotoxic risk. There is insufficient good data to prescribe a specific recommended threshold for iodinated contrast administration. The risk of CIN from IV iodinated contrast media appears to be sufficiently low such that a threshold of 2.0 mg/dL in the setting of stable chronic renal insufficiency is probably safe for most patients. For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the ACR Manual on Contrast Media (see the "Availability of Companion Documents" field).

Abbreviations

- AML, angiomyolipoma
- CIN, contrast-induced nephrotoxicity
- CT, computed tomography
- MRI, magnetic resonance imaging
- NSF, nephrogenic systemic fibrosis
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
<input type="text"/>	<0.1 mSv	<0.03 mSv
<input type="text"/> <input type="text"/>	0.1-1 mSv	0.03-0.3 mSv
<input type="text"/> <input type="text"/> <input type="text"/>	1-10 mSv	0.3-3 mSv
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	10-30 mSv	3-10 mSv
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	30-100 mSv	10-30 mSv

*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations

are designated as "Varies." Relative Radiation Level	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Indeterminate renal mass

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Internal Medicine

Nephrology

Oncology

Pathology

Radiology

Urology

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of radiologic examinations for patients with an indeterminate renal mass

Target Population

Patients with an indeterminate renal mass

Interventions and Practices Considered

1. X-ray intravenous urography
2. Ultrasound (US) kidney retroperitoneal with duplex Doppler
3. Computed tomography (CT) abdomen
 - Without and with contrast
 - With contrast
 - Without contrast
4. Magnetic resonance imaging (MRI) abdomen
 - Without and with contrast
 - Without contrast
5. Arteriography kidney
6. Biopsy renal mass

Major Outcomes Considered

- Utility of radiologic procedures in evaluation of indeterminate renal mass
- Sensitivity, specificity, accuracy, and positive and negative predictive value of radiologic procedures

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

Staff search in PubMed only for peer reviewed medical literature for routine searches. Any article or guideline may be used by the author in the narrative but those materials may have been identified outside of the routine literature search process.

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 10 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Study Quality Category Definitions

Category 1 - The study is well-designed and accounts for common biases.

Category 2 - The study is moderately well-designed and accounts for most common biases.

Category 3 - There are important study design limitations.

Category 4 - The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:

- a. The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description).
- b. The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence.
- c. The study is an expert opinion or consensus document.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence (study quality) for each article included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distribute surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The appropriateness rating scale is an ordinal scale that uses

integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate"; 4, 5, or 6 are in the category "may be appropriate"; and 7, 8, or 9 are in the category "usually appropriate." Each panel member assigns one rating for each procedure for a clinical scenario. The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating.

If consensus is reached, the median rating is assigned as the panel's final recommendation/rating. Consensus is defined as eighty percent (80%) agreement within a rating category. A maximum of three rounds may be conducted to reach consensus. Consensus among the panel members must be achieved to determine the final rating for each procedure.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is proposed as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

This modified Delphi method enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive influence from fellow panelists in a simple, standardized and economical process. A more detailed explanation of the complete process can be found in additional methodology documents found on the [ACR Web site](#) (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Decision-modeling studies have suggested that percutaneous biopsy is cost-effective and may play a greater role in the future in the diagnosis and management of the indeterminate renal mass.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for evaluation of patients with an indeterminate renal mass

Potential Harms

Contrast-induced Nephrotoxicity

Contrast-induced nephrotoxicity (CIN) is a sudden deterioration in renal function following the recent intravascular administration of iodinated contrast medium in the absence of another nephrotoxic event. There is consensus that the most important risk factor for CIN is pre-existing renal insufficiency. In patients with acute kidney injury, the administration of iodinated contrast medium should only be undertaken with appropriate caution and only if the benefit to the patient clearly outweighs the risk. Patients with acute kidney injury are particularly susceptible to nephrotoxin exposure and therefore it is probably prudent to avoid intravascular iodinated contrast medium in these patients (when possible), regardless of the generally low nephrotoxic risk. There is insufficient good data to prescribe a specific recommended threshold for iodinated contrast administration. The risk of CIN from intravenous (IV) iodinated contrast media appears to be sufficiently low such that a threshold of 2.0 mg/dL in the setting of stable chronic renal insufficiency is probably safe for most patients. For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Gadolinium-Based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the ACR Manual on Contrast Media (see the "Availability of Companion Documents" field).

Relative Radiation Level

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Contraindications

Contraindications

Contraindications to contrast-enhanced computed tomography (CT) include allergies to the contrast agent and renal insufficiency.

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA)

have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Heilbrun ME, Casalino DD, Beland MD, Bishoff JT, Blaufox MD, Coursey CA, Goldfarb S, Harvin HJ, Nikolaidis P, Preminger GM, Raman SS, Sahni VA, Vikram R, Weinfeld RM, Remer EM, Expert Panel on Urologic Imaging. ACR Appropriateness Criteria® indeterminate renal mass [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 11 p. [72 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1996 (revised 2014)

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

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Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Urologic Imaging

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Israel GM, Casalino DD, Remer EM, Arellano RS, Bishoff JT, Coursey CA, Dighe M, Eggi DF, Fulgham P, Goldfarb S, Lazarus E, Leyendecker JR, Nikolaidis P, Papanicolaou N, Prasad S, Ramchandani P, Sheth S, Vikram R, Expert Panel on Urologic Imaging. ACR Appropriateness Criteria® indeterminate renal masses. [online publication]. Reston (VA): American College of Radiology (ACR); 2010. 7 p. [66 references]

Guideline Availability

Electronic copies: Available from the [American College of Radiology \(ACR\) Web site](#) .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available from the [American College of Radiology \(ACR\) Web site](#) .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2013 Apr. 1 p. Electronic copies: Available from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2103 Nov. 3 p. Electronic copies: Available from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 90 p. Electronic copies: Available from the [ACR Web site](#) .
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available from the [ACR Web site](#) .
- ACR Appropriateness Criteria® indeterminate renal mass. Evidence table. Reston (VA): American College of Radiology; 2014. 28 p. Electronic copies: Available from the [ACR Web site](#) .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on March 7, 2006. This summary was updated by ECRI Institute on May 17, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 20, 2007 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This summary was updated by ECRI Institute on November 21, 2007 and June 4, 2010. This summary was updated by ECRI Institute on January 13, 2011 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This summary was updated by ECRI Institute on August 30, 2011 and July 31, 2014.

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